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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
07/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,687	CHEUNG, WING SUM	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1 - 13 in the reply filed on April 10, 2007 is acknowledged. Because the amendment filed with the response amended claims 14 – 15 to elected group, all claims now read on the elected invention.

Claim 13 is canceled; claims 1 – 12 and 14 – 15 are pending and have been considered on the merits.

Specification

2. The amendment filed April 10, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The phrase "kallikrein production inhibition activity" was not described in the specification as originally filed. The specification described a "kallikrein protease inhibition activity", which appears to be describing an activity that inhibits kallikrein protease. The new phrase "kallikrein production inhibition activity" appears to describe an activity that inhibits production of kallikrein, which is a different activity than inhibiting a kallikrein protease.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 – 12 and 14 – 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "kallikrein production inhibition activity" was not described in the specification as originally filed. The specification described a "kallikrein protease inhibition activity", which appears to be describing an activity that inhibits kallikrein protease. The new phrase "kallikrein production inhibition activity" appears to describe an activity that inhibits production of kallikrein, which is a different activity than inhibiting a kallikrein protease.

This is a new matter rejection.

5. Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 14 and 15 recite an "extract of the rabbit skin". These claims are considered genus claims that encompass a wide array of extracts. The specification fails to set forth a

representative number of examples in order to reasonably verify possession of such a potentially enormous number of extracts.

The MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that the claims are broad generics, with respect to *all* extracts that could be obtained from a rabbit skin (for example water, proteins, enzymes, oil, etc.). The instant disclosure fails to identify a single active extract of the rabbit skin. The possible variations of extracts are limitless with potentially hundred of types of extracts from a rabbit skin.

The purpose of the written description requirement is to ensure that the invention had possession, as of the filing date of the application, of the specific subject matter later claimed by him or her. A patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention. Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." The specification lacks sufficient variety of species of extracts to reflect this variance in the genus since the specification does not provide any examples of such a genus of extracts. Accordingly, the specification fails to provide adequate written description for the genus of "extract of a rabbit skin" and does not reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed had possession of the entire scope of the claimed invention. Moreover, the specification neither describes the complete structure of a representative number of species, nor describes a representative number of species in terms of

partial structure and relevant identifying characteristics. Absent of such teachings and guidance as to the structure and function of these extracts, the specification does not describe the claimed extract of a rabbit skin in such full, clear, concise and exact terms so as to indicate that Applicant had possession of these extracts at the time of filing of the present application. Thus, the written description requirement has not been satisfied.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1 – 12 and 14 – 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and its dependents are drawn to a rabbit skin, however are rendered vague and indefinite for reciting "feeding rabbit vaccinated with vaccinia virus" because it is unclear if the rabbit is being feed a virus, or if a rabbit who has been vaccinated is being fed food.

The claims are further indefinite for reciting "sufficiently inflamed" because it is unclear what constitutes "sufficiently inflamed", as the phrase has not been adequately defined by the claim language or specification.

Claim 6 is confusing for reciting "~" instead of "-" between the amounts, because it is unclear if the amounts are true ranges, or "about" ranges as the "~" is interpreted as "about".

In claim 12, line 2, "SART" lacks clarity in that it is not defined by the claim language or specification.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 – 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Shibayama et al. (US 5057324).

Applicant claims a rabbit skin containing kallikrein production inhibition activity wherein the skin is obtained by vaccinating rabbit skin tissues with vaccinia virus, feeding the rabbit, killing the rabbit when the skin tissues are inflamed, and skinning the rabbit. The virus is Lister strain, Ikeda strain, Dairen strain, EM-63 starin; the vaccinating is effected b injecting 0.1 – 0.4 ml solution containing 10^6 – 10^9 virus/ml each site, 100 – 250 cites per rabbit weighing 1.5 – 3Kg. The rabbit is a Japanese white, New Zealand white, Chinese or Blue-violet rabbit. The skin is inflamed when visible blains are present, the skin is red to mauve and thick, and the subcuticle hip is swollen; the skin possesses 0.5 iu/g SART activity.

Shibayama teaches a rabbit skin extract that has inhibitory activity against kallikrein formation, wherein the substance is useful as a drug (abstract). The substance is obtained by infecting a rabbit skin with vaccinia virus (col.1 line 45-65) and removing the skin (example 1). Shibayama teaches the extract in a drug composition with a pharmaceutically acceptable carrier (claims).

Although the reference does not expressly teach all of the limitations regarding how the rabbit skin is produced, these limitations are considered to be product by process type limitations. The patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1 – 12 and 14 – 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shibayama et al. (US 5057324).

Applicant claims a rabbit skin containing kallikrein production inhibition activity wherein the skin is obtained by vaccinating rabbit skin tissues with vaccinia virus, feeding the rabbit, killing the rabbit when the skin tissues are inflamed, and skinning the rabbit. The virus is Lister

strain, Ikeda strain, Dairen strain, EM-63 starin; the vaccinating is effected b injecting 0.1 – 0.4 ml solution containing 10^6 – 10^9 virus/ml each site, 100 – 250 cites per rabbit weighing 1.5 – 3Kg. The rabbit is a Japanese white, New Zealand white, Chinese or Blue-violet rabbit. The skin is inflamed when visible blains are present, the skin is red to mauve and thick, and the subcuticle hip is swollen; the skin possesses 0.5 iu/g SART activity. Applicant claims a drug and health food comprising water and an extract of the rabbit skin.

Shibayama teaches a rabbit skin extract that has inhibitory activity against kallikrein formation, wherein the substance is useful as a drug (abstract). The substance is obtained by infecting a rabbit skin with vaccinia virus (col.1 line 45-65). Shibayama teaches the extract in a drug composition with a pharmaceutically acceptable carrier (claims).

Although the reference does not expressly teach all of the limitations regarding how the rabbit skin is produced, these limitations are considered to be product by process type limitations. The patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

The reference does not teach feeding the rabbit. However as a matter of standard protocol, animals used in laboratory experiments are required to be treated humanely which includes feeding of the animals. Thus, while the reference does not expressly state the rabbits

were fed, it would have been a matter of standard procedure to do so, and thus obvious to one of ordinary skill in the art.

The reference does not teach each of the claimed strains of vaccinia, types of rabbit, wherein the inflammation reaches the claimed point, or SART activity of the skin. However, at the time of the claimed invention, each of the claimed strains and rabbits were well known and used in the art for animal and laboratory experiments. Thus, it would have been within the purview of one in the art to use any of the instant strains or rabbits as a matter of routine practice. Regarding the SART activity, the skin of the art is the same as that claimed, thus it must intrinsically exhibit the claimed activity.

The reference does not teach the amount of virus injected into the rabbit. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such injections as a matter of routine experimentation. Thus, one of ordinary skill in the art would have been motivated by routine practice to optimize the amount of virus injected into the rabbit with a reasonable expectation for successfully obtaining an effective extract against the formation of kallikrein.

The reference does not teach water as the pharmaceutically acceptable carrier. However, at the time of the claimed invention, water was a well known and recognized carrier. Thus it would have been obvious to one of ordinary skill in the art to combine the extract with water in following the teachings of Shibayama.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/
Primary Examiner
Art Unit 1651

July 6, 2007